

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of the effectiveness of two intravenous doses of ketorolac for the treatment of acute renal colic in patients referred to the emergency department

#### Protocol summary

##### Study aim

This study designed to compare the effect of two doses of 15 and 30 mg of Ketorolac in the treatment of acute pain in patients referred to renal colic in the emergency department of Khatam-al-Anbia Hospital in Zahedan

##### Design

A randomized clinical trial with parallel, double-blind, phase 2, on 160 patients, block randomization

##### Settings and conduct

Patients referred to the emergency room of Khatam-al-Abia Hospital in Zahedan who will be treated for renal colic based on clinical findings admitted. The diagnosis of renal colic is based on CT-scan without abdominal contrast. Patients are randomly divided into two groups receiving 15 or 30 mg ketorolac (prepared in 5 cc syringes with the same appearance) at the beginning of hospitalization. Participants and research evaluator isn't aware of the drug group. In cases where pain control isn't achieved with ketorolac injection, the intravenous morphine rescue dose of 0.1 mg/kg will be used as an alternative and the number of morphine rescue doses will be recorded. Vital signs and VAS will be assessed at the time of admission (before drug injection), 20, 40 and 60 minutes after injection.

##### Participants/Inclusion and exclusion criteria

Patients older than 16 years old with moderate to severe acute renal colic are included. Patients older than 70 years of age; pregnant or lactating; with gastrointestinal problems such as gastritis, peptic ulcer or acute bleeding; hypersensitivity to nonsteroidal anti-inflammatory drugs; unstable vital signs, and patients using analgesia medications are excluded.

##### Intervention groups

Patients in both groups are treated with 15 mg or 30 mg ketorolac. The effectiveness of the two doses of this drug and its side effects are evaluated, and if there is no response to treatment, the next treatment is the use of

morphine.

##### Main outcome variables

Reduction of numerical pain scale; vital signs; side effects; the need for life-saving pain relief; patient satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201018049062N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

##### Registration date

2020-11-18, 1399/08/28

##### Registrant information

##### Name

Sheida Mehrdad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3337 2114

##### Email address

sheida.mehrdad@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-05, 1399/09/15

##### Expected recruitment end date

2021-03-19, 1399/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of two intravenous doses of ketorolac for the treatment of acute renal colic in patients referred to the emergency department

**Public title**

Effect of two doses of ketorolac in the treatment of acute renal colic pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients over 16 years of age admitted to the emergency department due to renal colic

**Exclusion criteria:**

age older than 70 y/o Women during pregnancy or lactation Gastrointestinal problems such as gastritis, peptic ulcer or acute bleeding Allergy to nonsteroidal anti-inflammatory drugs Unstable vital signs (systolic BP less than 90 or more than 180 mm Hg, HR less than 50 or more than 150) Patients with a history of analgesia

**Age**

From **16 years** old to **70 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are randomly divided into two groups of 8 blocks. Thus, according to the order of patient placement in the group of 8 in each block, 4 patients from group A and 4 patients from group B will be randomly placed. Then, when referring, a block is selected, and based on the patient's entry order and the card row in each block, the patient will be assigned to the relevant group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drug groups will be prepared in doses of 15 mg (group A) and 30 mg (group B) in 5cc syringes with the same appearance. At the beginning of the hospitalization, patients are randomly divided into two groups receiving ketorolac (15 or 30 mg ketorolac). In one group, ketorolac at a dose of 15 mg (group A) is administered intravenously and in the other group, ketorolac at a dose of 30 mg (group B) is used intravenously. The classification of patients and the type

of medication used for the people involved in the study are blinded and the researcher evaluating the patients is not aware of the drug group prescribed to patients during the study. For this purpose, all syringes of both groups have the same appearance and volume with the same frequency of use in both groups. Other common treatments also apply to both groups. Therefore, the study will be conducted in a double-blind manner.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

**Street address**

Dr. Hesabi Square - Campus of Medical Sciences

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2020-10-11, 1399/07/20

**Ethics committee reference number**

IR.ZAUMS.REC.1399.309

**Health conditions studied****1****Description of health condition studied**

Renal Colic

**ICD-10 code**

N20.0

**ICD-10 code description**

Calculus of kidney

**Primary outcomes****1****Description**

Pain intensity score on a numerical pain scale

**Timepoint**

Measurement of pain intensity at the time of referral (before drug injection), 20, 40 and 60 minutes after drug injection

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Satisfaction with the type of treatment

#### Timepoint

60 minutes after receiving the drug

#### Method of measurement

5 point scale

### 2

#### Description

Side effects

#### Timepoint

60 minutes after drug injection

#### Method of measurement

Physical examination

### 3

#### Description

The need for a life-saving dose

#### Timepoint

After establishing painlessness

#### Method of measurement

Frequent administration of morphine rescue dose

### 4

#### Description

Heart Rate

#### Timepoint

20, 40 and 60 minutes after injection

#### Method of measurement

Number on monitoring

### 5

#### Description

Average Blood Pressure

#### Timepoint

20, 40 and 60 minutes after injection

#### Method of measurement

Number on monitoring

## Intervention groups

### 1

#### Description

Intervention group: Ketorolac group with a dose of 15 mg stat

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Ketorolac group with a dose of 30 mg stat

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam Al-Anbia Hospital in Zahedan

##### Full name of responsible person

Athare Nazri Panjaki

##### Street address

Jam Jam Boulevard, Khatam-Al-Anbia Hospital

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3337 2151

##### Email

athare.nazri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Ms. Moodi

##### Street address

Dr. Hesabi Square - Campus of Medical Sciences

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3337 2151

##### Email

public@zaums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Zahedan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sheida Mehrdad

**Position**

Emergency Medicine Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Khatam Al-Anbia Hospital, Jam Jam Square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3337 2155

**Email**

sheida.mehrdad@zaums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sheida Mehrdad

**Position**

Emergency Medicine Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Khatam Al-Anbia Hospital, Jam Jam Square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3337 2155

**Email**

sheida.mehrdad@zaums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sheida Mehrdad

**Position**

Emergency Medicine Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Khatam Al-Anbia Hospital, Jam Jam Square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3337 2155

**Email**

sheida.mehrdad@zaums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data is potentially shareable after unidentified individuals

### When the data will become available and for how long

Access period starts 5 months after the results are published

### To whom data/document is available

The data from this study will be available to academic and scientific researchers as well as people working in industry (if needed)

### Under which criteria data/document could be used

The data from the present study will be usable for other researchers, provided the source and citation are preserved.

### From where data/document is obtainable

Applicants can send their application through the mailing address sheida.mehrdad@zaums.ac.ir Dr. Sheida Mehrdad.

### What processes are involved for a request to access data/document

After sending a request to receive the documents to Dr. Sheida Mehrdad, he will check the identity of the applicant and the type of application and will send the documents in less than two weeks

### Comments